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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	10/042,421	SACKSTEIN, ROBERT	
	Examin r	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claim 8 links Inventions II-IV, claim 19 links Inventions V-VII, claims 26, 40 and 47 link Inventions VIII-IX, claim 27 links Inventions XI-XIII, claim 28 links Inventions XIV-XVI, claim 33 links XVII-XIX, claim 39 links Inventions XXII-XIV, claim 40 also links Inventions XXV-XXVII, claim 54 links Inventions XXX-XXXII, claim 56 links XXXIII-XXXV, claim 57 links Inventions XXXVI-XXXVIII, claim 58 links Inventions XXXIX-XLI and claim 59 links Inventions XLII-XLIV. The restriction requirement the linked inventions is subject to the nonallowance of the linking claim(s), claims 8, 19, 26, 27, 28, 33, 39, 40 ,47, 54, 56, 57, 58 and 59. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Given the ambiguity of the claimed recitation of claimed and disclosed
"agents that specifically binds to the glycosylated polypeptide",
"agents that increase cell-surface expression or activity of the glycosylated polypeptide",
"hematopoietic disorders" , "cancer", "inflammatory disorders" and "disorders amenable for treatment",
"stem cell populations isolated via "agents that specifically binds to the glycosylated polypeptide", "E-selectin", "L-selectin", applicant is invited to indicate how each of the claims are distinguishable.

In addition, applicant is invited to distinguish or clarify whether the preambles and endpoints are distinguishable or overlapping.

Clearly, these molecules do not share a substantial structural feature essential to a common utility. For example, antibodies, proteins and nucleic acids as well as nucleic acids encoding CD44, glycosyltransferase or glycosidase do not have a common structure that reads on a common utility.

Given the expression of CD44, E-selectin and L-selectin and their receptors on various cell populations, applicant is invited to clarify whether the stem cell populations isolated with anti-CD44 antibodies, E-selectin or L-selectin differ or not and to what degree.

Given that the body of certain claims appear to achieve the same or nearly the same endpoints, certain claims have been grouped together even though the preamble differs. Here too, applicant is invited to indicate whether or how the claimed methods are different to advance prosection.

Given the ambiguity of the intent as well as the scope of the instant claims, the instant application may be subject to further Restriction.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, drawn to a glycosylated polypeptide, classified in Class 530, subclass 350.

II. Claim 8-11, drawn to methods of identifying stem cells with glycosylated polypeptide specific agents (i.e. CD44- / HECA-452-specific antibodies), classified in Class 435, subclass 7.1.

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

III. Claim 8, 12, drawn to methods of identifying stem cells with E-selectin, classified in Class 435, subclass 4.

IV. Claims 8, 13-18, drawn to methods of identifying stem cells with L-selectin, classified in Class 435, subclass 4.

V. Claims 19-20, drawn to methods of isolating stem cells with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 435, subclass 2.

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

VI. Claim 19, 20, 21, drawn to methods of isolating stem cells with E-selectin, classified in Class 435, subclass 2.

VII. Claims 19, 20, 22-25, drawn to methods of isolating stem cells with L-selectin, classified in Class 435, subclass 2.

VIII. Claims 26, 40-45, 47, drawn to a method of treating a hemopoietic disorder (e.g. hemopoietic cancers) by administering stem cells isolated with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 424, subclass 93.1

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

IX. Claim 26, 40-45, 48 drawn to a method of treating a hemopoietic disorder (e.g. hemopoietic cancers) by administering stem cells isolated with E-selectin, classified in Class 424, subclass 93.1

X. Claim 26, 40-45, 49-52, drawn to a method of treating a hemopoietic disorder (e.g. hemopoietic cancers) by administering stem cells isolated with L-selectin, classified in Class 424, subclass 93.1

XI. Claim 27, drawn to a method of treating cancer (non-hematopoietic cancers) by administering stem cells isolated with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 424, subclass 93.1

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XII. Claim 27 drawn to a method of treating cancer (non-hematopoietic cancers) by administering stem cells isolated with E-selectin, classified in Class 424, subclass 93.1

XIII. Claim 27, drawn to a method of treating cancer (non-hematopoietic cancers) by administering stem cells isolated with L-selectin, classified in Class 424, subclass 93.1

XIV. Claims 28-30, drawn to a method of increasing the affinity of a cell for E-selectin and/or L-selectin, with a glycosylated polypeptide specific agents that is a nucleic acid that encodes CD44 classified in Class 435, subclass 375.

XV. Claims 28-29, 31-32, drawn to a method of increasing the affinity of a cell for E-selectin and/or L-selectin, with a glycosylated polypeptides specific agent that is a nucleic acid that encodes a glycosyltransferase classified in Class 435, subclass 375.

XVI. Claims 28-29, 31, drawn to a method of increasing the affinity of a cell for E-selectin and/or L-selectin, with a glycosylated polypeptides specific agent that is a nucleic acid that encodes a glycosidase, classified in Class 435, subclass 375.

XVII. Claims 33-34, drawn to a method of increasing the engraftment potential of a stem cell with a glycosylated polypeptides specific agent that is a nucleic acid that encodes CD44, classified in Class 435, subclass 377.

XVIII. Claims 33, 35, 36 drawn to a method of increasing the engraftment potential of a stem cell with a glycosylated polypeptides specific agent that is a nucleic acid that encodes a glycotransferase, classified in Class 435, subclass 377.

XIX. Claims 33, 35, drawn to a method of increasing the engraftment potential of a stem cell with a glycosylated polypeptides specific agent that is a nucleic acid that encodes glycosidase, classified in Class 435, subclass 377.

XX. Claim 37, drawn to a method of increasing the engraftment potential of a stem cell with L-selectin, classified in Class 435, subclass 377.

XXI. Claim 38, drawn to a method of increasing the engraftment potential of a stem cell with E-selectin, classified in Class 435, subclass 377.

XXII. Claim 39, drawn to a method of increasing the levels of engrafted stem cells by administering an agent that increases cell-surface expression of the glycosylated polypeptide that is a nucleic acid that encodes CD44, classified in Class 514, subclass 44.

XXIII. Claim 39, drawn to a method of increasing the levels of engrafted stem cells by administering an agent that increases cell-surface expression of the glycosylated polypeptide that is a nucleic acid that encodes glycotransferase, classified in Class 514, subclass 44.

XXIV. Claim 39, drawn to a method of increasing the levels of engrafted stem cells by administering an agent that increases cell-surface expression of the a glycosylated polypeptide agent that is a nucleic acid that encodes glycosidase, classified in Class 514, subclass 44.

XXV. Claims 40-45, drawn to a method of increasing the levels of engrafted stem cells by administering cells isolated with a glycosylated polypeptide specific agent that is a nucleic acid that encodes CD44, classified in Class 424, subclass 93.1

For examination purposes, Groups XXV/XXVI/XXVII are considered drawn to treating hemopoietic disorders (e.g hemopoietic cancers). If applicant intends that therapeutic endpoints to read on treating cancer, inflammatory diseases or disorders amenable to treatment, then such claims will be subject to further Restriction.

XXVI. Claims 40-45, drawn to a method of increasing the levels of engrafted stem cells by administering cells isolated with glycosylated polypeptide specific agent that is a nucleic acid that encodes glycotransferase, classified in Class 424, subclass 93.1

XXVII. Claims 40-45, drawn to a method of increasing the levels of engrafted stem cells by administering cells isolated with a glycosylated polypeptides specific agent that is a nucleic acid that encodes glycosidase, classified in Class 424, subclass 93.1

XXVIII. Claim 46, drawn to a method of treating a hemopoietic disorder (e.g. hemopoietic cancers) with an an agent that decreases the cell surface or expression of the glycosylated polypeptide, classified in Class 514, subclass 8.

Applicant is invited to indicate what agents are encompassed by this claim. Such claims would be subject to further Restriction.

XXIX. Claim 53 drawn to a method of treating inflammatory disorders by administering a glycosylated polypeptide, classified in Class 514, subclass 8.

XXX. Claims 54-55, drawn to a method of treating a disorder amenable for treatment by administering stem cells isolated with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 424, subclass 93.1

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XXXI. Claims 54-55 drawn to a method of treating a disorder amenable for treatment by administering stem cells isolated with E-selectin, classified in Class 424, subclass 93.1

XXXII. Claim 54-55, drawn to a method of treating a disorder amenable for treatment by administering stem cells isolated with L-selectin, classified in Class 424, subclass 93.1

XXXIII. Claim 56, drawn to a method of diagnosing susceptibility to a hematologic disorder by by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 435, subclass 7.1

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XXXIV. Claim 56, drawn to a method of diagnosing susceptibility to a hematologic disorder by by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is E-selectin, classified in Class 435, subclass 4

XXXV. Claim 56, drawn to a method of diagnosing susceptibility to a hematologic disorder by by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is L-selectin, classified in Class 435, subclass 4

XXXVI. Claim 57, drawn to a method of determining prognosis of efficacy of treatment of a hematological disorder by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is CD44- / HECA-452-specific antibody, classified in Class 435, subclass 7.1

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XXXVII. Claim 57, drawn to a method of determining prognosis of efficacy of treatment of a hematological disorder by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is E-selectin, classified in Class 435, subclass 4

XXXVIII. Claim 57, drawn to a method of determining prognosis of efficacy of treatment of a hematological disorder by detecting the glycosylated polypeptide with a glycosylated polypeptide specific agent that is L-selectin, classified in Class 435, subclass 4

XXXIX. Claim 58 drawn to a method of treating a hemopoietic disorder with a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 424, subclass 130.1.

If applicant intends to claim an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XL. Claim 58 drawn to a method of treating a hemopoietic disorder with a glycosylated polypeptide specific agent that is E-selectin, classified in Class 514, subclass 8.

XLI. Claim 58 drawn to a method of treating a hemopoietic disorder with a glycosylated polypeptide specific agent that is L-selectin, classified in Class 514, subclass 8.

XLII. Claim 59-61 drawn to a method of treating a hemopoietic disorder with a two domain agent wherein the first domain is a glycosylated polypeptide specific agent that is a CD44- / HECA-452-specific antibody, classified in Class 424, subclass 130.1

If applicant intends to claim with a two domain agent wherein the first domain is a an agent other than CD44- / HECA-452-specific antibodies, E-selectin or L-selectin, then applicant should indicate this and such limitations will be subject to further Restriction.

XLIII. Claim 59, 61 drawn to a method of treating a hemopoietic disorder with a two domain agent wherein the first domain is a glycosylated polypeptide specific agent that is E-selectin, classified in Class 514, subclass 8.

XLIV. Claim 59, 61 drawn to a method of treating a hemopoietic disorder with with a two domain agent wherein the first domain is a glycosylated polypeptide specific agent that is L-selectin, classified in Class 514, subclass 8.

3. Inventions I and XXIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as affinity purification procedures or detection assays. In addition, there have been a myriad of agents employed to treat hemopoietic disorders other than the glycosylated protein.

4. Inventions II - XLIV are different methods of use. These inventions require different ingredients, process steps and endpoints. Therefore they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XLIV is not required for any other group from Groups I-XLIV and Groups I-XLIV have acquired a separate status in the art because they encompass divergent subject matter and non-coextensive searches, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed Groups VIII-X, XXV-XXVIII, XXXIII-ILIV, wherein the hematopoietic disorder (e.g. see page 30, paragraph 1) is:

A) leukemia,
B) aplastic anemia,
C) non-Hodgkin's lymphoma,
D) chronic myeloid leukemia,
E) multiple myeloma,
F) chronic lymphocytic leukemia, or
G) various myelodysplastic syndromes .

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. This application contains claims directed to the following patentably distinct species of the claimed Groups XXX-XXXII, wherein the disorder amenable to treatment with a stem cell (e.g. see page 26, paragraph 2) is:

A) myocardial infarction,
B) Parkinson's disease,
C) diabetes,
D) congenital muscle dystrophies,
E) stroke,
F) genetic/congenital disorders (e.g. osteogenesis imperfecta), or
G) liver disorders.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 17, 2003